**Declaration of David F. Stitt, R.Ph.**

My Background

1. My name is David F. Stitt. I have been a registered pharmacist in New York since 1976 and am a Certified Geriatric Pharmacist. I have a Bachelor of Science degree in Pharmacy from the Albany College of Pharmacy and an MBA from Union College.

2. I am currently Director of Pharmacy at MVP Health Care ("MVP"), located at 625 State Street, Schenectady, New York. I am also a Consultant Pharmacist for long term care. I have held both positions for over 14 years.

3. As Director of Pharmacy at MVP, I participate in the operations of MVP's prescription drug program. In this role, my duties include formulary and policy development, drug utilization management oversight, and working with MVP's Pharmacy Benefits Manager on formulary placement of pharmaceuticals. I am also a member of MVP's Pharmacy & Therapeutics Committee.

4. MVP is a regional not-for-profit health plan serving over 700,000 members across New York, Vermont, and New Hampshire. MVPoffers its members a health care provider network that includes more than 19,000 regional health care providers and facilities, and a national network of more than 500,000 providers.

5. MVP offers various types of health plans, including commercial plans, Medicaid Managed Care plans, Medicare Advantage plans, and Medicare Part D plans. MVP offers prescription drug coverage as part of these plans.

MVP's Use of Formularies

6. For each plan in which MVP offers prescription drug coverage, MVP creates a list – called a "formulary" – of approved drugs covered by the plan, along with any requirements or limits on coverage for each drug listed. The formulary represents the prescription therapies believed to be a necessary part of a quality treatment program.

7. In addition to ensuring that members have access to medically necessary and appropriate prescription drugs for common diseases and medical conditions, MVP uses formulary placement in an effort to influence choices of drugs for plan members so as to help contain cost while promoting safety and efficacy. Typically, placing a drug on a lower tier provides incentives to plan members to purchase those drugs instead of drugs on higher tiers. As explained in more detail below, formulary placement can sometimes, but not always, have an impact on drug selection by plan members.

8. As with other health plans, while MVP does not purchase drugs directly, MVP pays (or reimburses) for covered drugs purchased by MVP plan members. To do so, MVP's Pharmacy Benefits Manager negotiates with pharmaceutical manufactures – including Actavis (and formerly Forest Labs) – over the prices that MVP will pay for these covered drugs.

9. MVP's formularies place each covered drug into one of several "tiers" (or cost groups) reflecting the different co-pays (that it requires its plan members to pay when acquiring the drugs) and any other requirements or limits on the drug's coverage. A typical formulary used by MVP has between 2-3 tiers, with Tier 1 including preferred generic drugs, Tier 2 including preferred branded drugs, and Tier 3 including non-preferred drugs. Drugs listed in lower tiers typically have lower co-payments and fewer

requirements or limits (if any) than drugs on higher tiers. Thus, for example, on MVP's current GoldValue HMO-POS Medicare Part D plan, the co-payments for the first three tiers are as follows: Tier 1 (preferred generic drugs) = $10; Tier 2 (preferred branded drugs) = $35; and Tier 3 (non-preferred drugs) = $90.

10. While not all covered generic drugs are listed on Tier 1 of a formulary, the majority of generic drugs covered on an MVP plan are placed on that tier.

11. MVP typically places generic drugs on Tier 1 of its formularies because generics are usually much less expensive than a branded version of the same drug, while being clinically and therapeutically equivalent to the branded version. In general, MVP's cost for a generic version of a drug is much less than for the branded version of the drug – especially when there are multiple companies selling generic versions of the same branded drug. Thus, in general, generic drugs lower MVP's cost, which enables MVP to charge lower premiums to its members. This is why MVP generally places generic drugs on a lower tier than branded drugs.

12. When an AB-rated (described below) generic version of a branded drug that is already covered on a MVP formulary becomes available, the generic version of the drug is usually placed on Tier 1 of the formulary.

13. MVP's formularies, and all drugs listed on the formularies, are reviewed by a Pharmacy & Therapeutics ("P&T") Committee. The P&T Committee consists of MVP staff as well as non-MVP community physicians, specialist and pharmacists. The P&T Committee meets a number of times each year to review formularies and evaluate the placement of both new and existing drugs on formularies. MVP uses the services of

a Pharmacy Benefits Manager to assist the P&T Committee in creating and managing MVP's formularies.

14. MVP and its P&T Committee consider various factors in deciding which drugs to cover on a formulary, on which tier to place each drug, and whether to recommend any requirements or limits on any particular drug. For example, in evaluating whether to add a new drug to a formulary, the P&T Committee evaluates whether or not the new drug has significant clinical and therapeutic advantages over drugs used to treat the same disease or condition that are already covered on the formulary. Other factors that MVP may consider are cost, the number of other drugs on the formulary that are used to treat the same disease or condition, and any disadvantages of a particular drug, *e.g.* side effects or safety concerns.

15. The P&T Committee reviews all formulary policies and drug classes or categories at least annually.

Utilization Management Tools

16. In addition to deciding which drugs to place on a formulary and on what tier, the P&T Committee recommends whether each drug listed on a formulary should be subject to any requirements or limits. Common requirements and limits used on MVP formularies are utilization management tools such as prior authorization, step therapy, and quantity limits. These requirements and limits are instituted in an attempt to maximize the possibility that covered drugs are appropriately utilized.

17. "Prior authorization" refers to when a member (or his physician) is required to obtain MVP approval prior to having a prescription for a covered drug

dispensed, in order to obtain reimbursement from MVP. "Step therapy" refers to when MVP requires that a member (or her physician) try a covered drug for the same medical condition prior to MVP authorizing approval for a particular drug. "Quantity limits" refers to when MVP limits the quantities of a drug that it will cover during a particular time period.

18. Utilization management tools typically result in significant costs, both for MVP as well as health care professionals. For example, because prior authorization requires MVP approval prior to a pharmacist dispensing the drug (or alternatively, a new prescription for a different drug), it typically requires communications between the pharmacist, physicians, and/or MVP, and well as possibly submission and review of a prior authorization form. MVP's cost for prior authorization is high – typically in the range of between $40 to $120 per prior authorization request. My understanding is this cost range for prior authorization is typical for other insurers as well. Prior authorization may also impose direct and indirect cost on pharmacists and physicians, such as the time required to communicate and submit necessary forms.

19. MVP has used utilization management in an effort to encourage physicians to prescribe one drug over another, when appropriate. The decision of whether to implement utilization management to encourage use of any particular drug is reviewed by MVP's P&T Committee.

20. In my experience, the success of utilization management tools to encourage physicians to prescribe one drug over another depends on numerous factors, including safety and efficacy of the drugs being considered, the number of different drugs in the same drug class or category as the drug subject to utilization management,

physicians' medical opinions as to the advantages and disadvantages between these drugs, differences in cost to patients, and how and when the particular utilization management tool is implemented.

Generic Drugs

21. While MVP could implement utilization management to encourage the use of generics, it typically relies on state substitution laws and differential tiering on its formularies. Most states – including New York – have laws requiring a pharmacist to dispense a generic drug deemed by the Food and Drug Administration ("FDA") to be bioequivalent – "AB-rated" – to an already approved branded drug. Thus, for example, a pharmacist in New York that receives a prescription for a branded drug for which there is an AB-rated generic, will dispense the AB-rated generic unless "Dispense as Written" is indicated on the prescription. Because the generic is AB-rated and preferred by MVP, the pharmacist will be informed via his prescription dispensing software that there is a generic available with a lower co-pay. At that point, MVP members will typically purchase the generic product.

22. In my experience with MVP's members, the substitution of AB-rated generic drugs for the branded equivalents, through the applicability of state generic substitution laws, is the only method by which generic drugs achieve significant sales. In my experience, generic drugs are not generally marketed or detailed to physicians or patients. In my experience, typically within three to six months after the AB-rated generic version is placed on the formulary, the majority of reimbursements paid by MVP will be for generic version rather than the branded version of the drug.

Namenda

23. MVP offers various health plans that cover its members' use of Namenda and/or Namenda XR. MVP reimburses for approximately 1,000 prescriptions of Namenda or Namenda XR per month. It is my understanding that there is currently no generic version of Namenda, but that a generic version is expected to be available around July 2015.

24. The vast majority of MVP's Namenda reimbursements are from its Medicare Part D plans. MVP has offered Namenda on its Medicare Part D plan formulary for a number of years.

25. MVP only recently placed Namenda XR on its formularies for various plans. Last year, prior to Namenda XR being launched, MVP's P&T Committee met to review whether to add Namenda XR to MVP's formularies, and if so, on which tier. The P&T Committee placed Namenda XR on Tier 2 in its formularies (the same tier as Namenda IR).

26. Namenda and Namenda XR are the only NMDA antagonists on MVP's formularies, and to my knowledge, the only NMDA antagonists approved by FDA.

27. On February 14, 2014, Forest Labs announced that it planned to discontinue Namenda on August 15, 2014.

Effect of Namenda Discontinuance on MVP's Medicare Part D Plans

28. Medicare Part D plans are regulated by the United States Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS"). CMS has numerous requirements for Medicare Part D plans. For example, CMS must approve the formulary for any Medicare Part D plan, as well as changes to the formulary. Formularies used in Medicare Part D plans must include drugs categories and classes that cover all disease states.

29. Companies like MVP seeking to offer Medicare Part D plans for any particular calendar year, must submit initial bids to CMS by the prior June. Thus, for calendar year 2015 (January 1, 2015 – December 31, 2015), initial bids were due to CMS this past June. A bid seeking to offer a Medicare Part D plan must include its formulary list of all drugs that the plan, if approved, will cover.

30. CMS utilizes a list of drugs called a Formulary Reference File to assist plans in preparing their bids. For calendar year 2015, Namenda was not on the Formulary Reference File, and therefore MVP did not include Namenda on its Medicare Part D formulary bid but instead added Namenda XR. I believe that other plans use the Formulary Reference File in preparing bids as well.

31. MVP has already submitted its initial bid to CMS for those Medicare Part D plans that will be offered for calendar year 2015. For the reasons mentioned above, MVP's bid for its 2015 Medicare Part D plans does not include Namenda on its proposed formulary.

32. On June 10, 2014, Forest announced that it planned to continue manufacturing Namenda into fall 2014. And it is my understanding that since that date,

Actavis has not made any further public announcements on its plans for manufacturing or discontinuing Namenda.

33. Due to the uncertainly of when Namenda will be discontinued, MVP has not taken any action to amend its 2015 bid to CMS for its proposed Medicare Part D plan offerings.

MVP's Plans for Generic Namenda

34. MVP has not yet decided what it will do when generic Namenda becomes available in July 2015. Based on my prior experience, I expect that after generic Namenda becomes available (*i.e.*, actually in stock on retail pharmacy shelves), it will be placed on Tier 1 – thus likely having a lower cost and co-payment than Namenda XR. At that time, MVP may move Namenda XR to a higher tier, but that has not been decided yet.

35. Actavis' decision to discontinue Namenda is likely to be very costly for MVP and its members – and certainly more costly than if Actavis continued to sell Namenda. Because Namenda and Namenda XR are the only NMDA antagonists on MVP's formularies, I expect that the vast majority of MVP members taking Namenda are likely to switch to Namenda XR if Namenda is discontinued this fall, as Actavis has indicated. And although MVP members could switch to generic Namenda when it becomes available, in practice I do not expect that most will because it is not AB-rated to Namenda XR.

36. A large portion of the financial losses caused by an MVP member's use of Namenda XR instead of generic Namenda will initially be borne by MVP, not physicians

or patients. While Namenda XR is currently a little less expensive than Namenda, I expect that generic Namenda will be substantially less expensive than Namenda XR within six months of its availability. Thus, once generic Namenda becomes available in July 2015, MVP will incur substantially higher costs for its member who were forced to switch to Namenda XR due to the discontinuance of Namenda, but did not switch to generic Namenda. These same patients will also continue to pay a higher co-pay for Namenda XR than they otherwise would pay for generic Namenda (due to the generic being on a preferred tier). In my experience, most physicians do not switch patients from a newer to an older formulation of the same drug unless either requested by patients or if an insurer is able to institute a successful utilization management tool. In the case of Namenda, I do not expect that either of those events will occur.

37. Based on my experience, I do not expect that most MVP members who have been switched to Namenda XR will ask their physicians to switch to generic Namenda when it becomes available. This is true in large part because of a number of information limitations faced by physicians, patients, and pharmacists.

38. First, based on my experience, I have doubts as to whether many patients or physicians will even be aware when generic Namenda becomes available. Generic drug manufacturers do not typically promote the availability of a new generic drug to patients or physicians. In addition, because generic Namenda is not AB-rated to Namenda XR, a pharmacist filling a prescription for Namenda XR may not be reminded via his prescription dispensing software that a generic alternative is available. And even if the pharmacist knew of the availability of generic Namenda, she could not dispense

generic Namenda without physician approval (or a new prescription) – which would require contacting a physician and possibly having to wait and submit forms.

39. Second, I do not expect that preferential formulary placement of generic Namenda as compared to Namenda XR will be sufficient to influence a significant number of patients or their caregivers to ask their physicians to switch them back from Namenda XR to Namenda. As mentioned earlier, neither members nor physicians may even be aware of the existence of a low-priced generic, and if so, probably not until the member is at the pharmacy attempting to have a prescription filled. At that time, even if members somehow became aware of the availability of generic Namenda and its lower co-pay, I do not expect a significant number of members to contact their doctors' offices in an effort to obtain a prescription for the lower-priced generic. Instead, in my experience, even patients that would likely have preferred to switch to a lower co-pay drug frequently end up paying the higher co-pay – likely due to reluctance to contact their physicians again, or the feeling that they do not have much choice.

40. Accordingly, while the co-pay differences represented by differential tier placement may sometimes influence drug selection, in this case I do not believe that preferential formulary placement by itself, *i.e.* absent automatic generic substitution, is likely to cause significant numbers of patients to switch (again) from Namenda XR to generic Namenda.

41. Thus, based on my experience, absent the use of utilization management strategies by MVP, most MVP patients taking Namenda XR will not switch to generic Namenda once it becomes available, even if it would be in their (and MVP's) best interests to do so.

Utilization Management Tools

42. Based on my experience, I also do not expect that utilization management tools such as prior authorization or step therapy will successfully switch most members currently taking Namenda XR to generic Namenda. And use of utilization management tools would entail substantial costs for MVP and may not be cost effective.

43. To begin with, I am not confident that MVP will decide to implement any utilization management tools at all (other than preferential tier placement for generic Namenda) in an effort to move patients from Namenda XR to generic Namenda. It is certainly possible that MVP will do so, but I cannot predict whether that will happen at this time.

44. There are several reasons why MVP may choose to not implement utilization management tools for this purpose – or, even if it did – why these tools might not be effective at encouraging MVP members taking Namenda XR to switch to generic Namenda.

45. First, even if MVP chooses to implement step therapy or prior authorization for Namenda XR, it is likely to feel compelled not to apply these rules to members who are already taking Namenda XR. This is because MVP is very reluctant to implement rules that would require a patient to stop taking a medication that a member is already taking, and doing well on. This is particularly true for a highly vulnerable patient population such as Alzheimer's patients. MVP has tools that would allow it to apply utilization management tools only to new patients prescribed Namenda XR, and may decide to do so, but may also decide that the benefits of seeking to move this smaller group of members is not worth the costs.

46. Second, most members taking Namenda are covered by Medicare, and MVP would need approval from CMS prior to implementing any utilization management tools relating to Namenda for these patients. CMS is often reluctant to agree to change utilization rules mid-year that impact Medicare patients, and the negotiations with CMS over these types of issues can take significant time, with no guarantee of success.

47. Third, even if MVP did decide to apply utilization management tools to patients already taking Namenda XR, and even if CMS approved this, it is speculative how many patients would actually be switched over. Because physicians are also reluctant to switch patients to a different drug when the patient is already doing well on the current drug they are taking, a significant number of physicians may be willing to request prior authorization or advocate for the medical necessity of a patient staying on Namenda XR, even if these physicians would have preferred that the patient never have switched from Namenda to Namenda XR. In addition, in situations where a patient is cared for by numerous people (such as a caregiver and family members), physicians tend to be even more reluctant to switch their medications, due to the need to ensure that not only the patient –but also numerous others – need to be adequately educated on how the medication is taken. Step therapy or prior authorization may thus not succeed in moving more than 50% of Namenda XR patients to generic Namenda –and could be significantly less successful.

48. Fourth, there may also be technical problems that might limit the success of utilization management at moving members from Namenda XR to generic Namenda. For example, step therapy frequently involves requiring a patient to engage in a trial of a less expensive drug prior to taking the more expensive drug. Here, the potential "step"

would be to ask members to take generic Namenda instead of Namenda XR. However, the computer software used by MVP and pharmacists to implement step therapy often provides an automatic exception to step therapy for patients who have already been on the "step" drug. In most cases, this allows a patient who failed on a trial with a less expensive drug to move automatically to the more expensive drug. Here, however, because all patients that switched from Namenda IR to Namenda XR as a result of Actavis' discontinuance of Namenda IR will already have a record in their histories of having taken Namenda IR, the software may identify these patients as exceptions to the "step" requirement (thereby impeding the effectiveness of the tool). The software is unable to discern which patients on Namenda XR who previously took Namenda IR were switched to Namenda XR for clinical reasons, or solely as a result of the discontinuance of Namenda IR.

49. In addition, in my experience, step therapy and prior authorization are more effective for drugs that have numerous substitutes. In this case, other than Namenda XR, the only other FDA approved NMDA antagonist is Namenda and generic Namenda. The lack of available substitutes for NMDA antagonists further suggests that utilization management strategies are less likely to be effective, or cost effective, at moving patients from Namenda XR to generic Namenda.

50. Finally, using these strategies would entail substantial costs to MVP.

Impact of Discontinuance

51. Because I do not believe that most MVP patients will in fact switch from Namenda XR to generic Namenda, I believe that discontinuing Namenda IR will impose significant, unnecessary costs on both MVP and patients.

52. First, because generic Namenda will almost certainly be on a lower tier than Namenda XR, patients who were switched to Namenda XR because of Namenda's discontinuance and do not switch back to generic Namenda, will be paying a higher co-payment than they otherwise would have been had Namenda not been discontinued.

53. Second, in my experience, there is a risk that elderly populations respond to higher co-pays by deciding not to purchase the prescribed drugs, or not taking it as frequently as prescribed. This poses a health risk for patients, and also raises the concern that failure to take the medications as prescribed will result in additional health care burdens.

54. Third, because Namenda XR will likely cost MVP dramatically more to reimburse for than generic Namenda, MVP will likely have to pay much more to cover its members' costs for taking an NMDA antagonist than would be necessary if these patients had stayed on, or switched back to, Namenda.

55. In the long run, strategies like Actavis' planned discontinuance of Namenda result in higher premiums for patients, because as the costs for caring for MVP's members increase, those costs end up being passed on to patients in the form of higher premiums. For example, the discontinuance of Namenda will make it more likely that MVP will be required to increase the amount it seeks from New York State for covering the costs of care for Managed Medicaid patients in New York.

56. I believe that if Actavis is permitted to accomplish the "forced switch" of patients from Namenda to Namenda XR, it will hurt patients, impose significant costs on MVP, and harm the economics of the health care delivery system. If additional companies also embark on this strategy, the resulting significant and unnecessary costs to patients and the health care system more generally could be enormous.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 11, 2014.

David F. Stitt, R.Ph.